MOTION FILED
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No. 92-800

IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Petitioner,

v.

KATHLEEN E. LES, *ET AL.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF THE GROCERY MANUFACTURERS OF AMERICA, INC., THE NATIONAL FOOD PROCESSORS ASSOCIATION, AND TEN OTHER FOOD INDUSTRY TRADE ASSOCIATIONS* AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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AMERICAN FROZEN FOOD INSTITUTE

AMERICAN SPICE TRADE ASSOCIATION

CHOCOLATE MANUFACTURERS ASSOCIATION

INTERNATIONAL DAIRY FOODS ASSOCIATION

NATIONAL CONFECTIONERS ASSOCIATION

NATIONAL COUNCIL OF FARMER COOPERATIVES

PRODUCE MARKETING ASSOCIATION

SNACK FOOD ASSOCIATION

UNITED FRESH FRUIT AND VEGETABLE ASSOCIATION

MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

Movants are food industry trade associations having a substantial interest in the outcome of this case. The member companies of these associations together produce the bulk of consumer food products subject to the food additive provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 348) including the Delaney Clause (21 U.S.C. 348(c)(3)(A)), and they therefore have a vital interest in urging that the decision of the court of appeals interpreting that provision be reviewed by this Court. By this motion, they request leave to file the accompanying brief as *amici curiae* in support of petitioner.

Movant Grocery Manufacturers of America, Inc. (GMA) submitted an *amicus* brief in the court of appeals with the consent of all parties. Movants National Food Processors Association (NFPA) and United Fresh Fruit and Vegetable Association have petitioned the Environmental Protection Agency (EPA) in the matter cited in footnote six of the Federal respondents' brief in opposition. The government's reference to that petition recognizes the important interest of the food industry in this case.

Petitioner and the Federal respondent have consented to the filing of the accompanying brief in this Court, and their consents are on file with the Clerk. Counsel for the non-Federal respondents has refused to consent, necessitating the submission of this motion pursuant to Rule 37 of the Rules of this Court.

GMA is a national trade association of more than 130 companies that manufacture and distribute products primarily sold in retail grocery stores throughout the United States. GMA's member companies employ more than 2.5 million people and have annual sales of more than $250 billion.

NFPA is the science-based association of the food industry, whose 500 members manufacture the nation's

processed packaged fruits and vegetables, juices and drinks, meat and poultry, seafood, and specialty products.

The American Bakers Association (ABA) is the national trade association representing the wholesale baking industry. The membership of the ABA consists of 200 baker members and 174 allied members who together manufacture approximately 85 percent of the baked goods sold in the United States.

The American Frozen Food Institute (AFFI) is a national trade association representing frozen food processors and companies that supply goods and services to the frozen food processing industry. AFFI's 550 corporate members produce over 90 percent of the total U.S. production of frozen food.

The American Spice Trade Association (ASTA) was founded in 1907 by the people who brought spices to the United States. The membership currently includes growers, overseas shippers, agents, brokers, importers, processors and dehydrators in this country, as well as many firms associated and allied with the industry. ASTA represents more than 300 member firms worldwide and is active in research, trade relations within and outside the industry, and spice education.

The Chocolate Manufacturers Association and the National Confectioners Association together represent the 97 companies who are responsible for the substantial majority of the sales of confectionery products in the United States. The confectionery industry is a significant user of agricultural commodities, being the second largest user of sugar, after baked products, and the third largest user of peanuts, after peanut butter and salted nuts, and a user of about four billion pounds of milk and milk products annually.

The International Dairy Foods Association (IDFA) is a national trade association representing three affiliated organizations, the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute.

These organizations together represent approximately 700 member companies which account for 85 percent of the processors and manufacturers of dairy foods in the United States.

The National Council of Farmer Cooperatives is a nationwide association of cooperative businesses which are owned and controlled by farmers. Its membership includes over 100 agricultural marketing, supply and credit cooperatives, plus 32 state councils. National Council members handle practically every type of agricultural commodity produced in the United States, market these commodities domestically and around the world, and furnish production supplies and credit to their farmer members and patrons. The National Council represents about 90 percent of the nearly 5,000 local farmer cooperatives in the nation, with a combined membership of nearly 2 million farmers.

The Produce Marketing Association (PMA) is the largest national trade association representing companies that market fresh fruits, vegetables, and floral products. PMA's membership of 2,650 includes growers, supermarket retailers, food service operators, and importers. Domestically, PMA members handle more than 90 percent of fresh produce sold.

The Snack Food Association is the trade association representing more than 500 domestic manufacturers and suppliers involved in the production and distribution of snack food products made from vegetables, grains, fruits, meats, and nuts consumed in the United States. While there are nationwide companies in the association, many are moderately sized regional businesses.

The United Fresh Fruit and Vegetable Association is the national trade organization which represents all sectors of the fresh produce industry. Founded in 1904, its 2,100 member firms are grower/shippers, brokers, truckers and other transportation specialists, wholesalers, foodservice distributors

and operators, retailers, allied suppliers and related educational and scientific organizations in the United States and abroad.

* * * *

The decision of the court of appeals that petitioner National Agricultural Chemicals Association asks this Court to review, if allowed to stand, would produce grave and far-reaching consequences for the cost and availability of the food supply and the nutritional health of consumers without any compensating public benefit. The decision would ban numerous invaluable pesticides which the EPA finds present only a *de minimis* risk to health while undermining the agricultural production, quality, and availability of fruit, vegetable, and grain products which public health officials have determined are essential for good health.

The food industry trade associations on many other occasions and in other cases have acted vigorously to protect the rights of their member companies and food consumers and to express their views on important issues relating to the regulation of the food supply. GMA did so in this case through the brief it filed as *amicus curiae* in the Ninth Circuit. The food industry associations believe that the attached brief can make an important contribution to the Court's decision whether to grant the petition for a writ of certiorari in this case. The brief supplements and is not redundant with the arguments presented in the petition for a writ for certiorari and documents the serious adverse consequences of the court of appeals' decision with respect to the food supply. As the attached brief shows, the court of appeals overstepped its authority by rejecting EPA's reasonable interpretation of the FFDCA in contravention of the now well settled doctrines of statutory interpretation established by this Court, and its decision should be overturned.

Accordingly, the food industry trade associations move for leave to file the attached brief *amici curiae*.

Respectfully submitted,

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QUESTION PRESENTED

Whether the Environmental Protection Agency reasonably construed the food additive Delaney Clause, 21 U.S.C. 348(c)(3)(A), to permit the continued use of substances that present only a *de minimis* risk of cancer.

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INTEREST OF THE *AMICI CURIAE*

As shown in the foregoing motion, *amici* are national food trade associations having a substantial interest in the outcome of this case.

STATEMENT OF THE CASE

Respondents Kathleen E. Les *et al.* sought direct review in the United States Court of Appeals for the Ninth Circuit of a final order of the Environmental Protection Agency (EPA) refusing to revoke approvals for certain pesticides. Petitioner National Agricultural Chemicals Association intervened in the court of appeals in support of the EPA's order. The court of appeals set aside the order, and this petition followed.

1. Respondents filed a petition with EPA on May 25, 1989, requesting that EPA revoke eleven food additive regulations covering seven pesticides. *See* 54 Fed. Reg. 27700 (June 30, 1989). EPA initially granted the petition in part and denied it in part, determining in particular that it would not revoke the approvals for pesticides presenting a negligible or *de minimis* risk of cancer to humans. *See* 55 Fed. Reg. 17560 (April 25, 1990). Respondents objected to EPA's decision on May 22, 1990. *See* 55 Fed. Reg. 26498 (June 28, 1990). EPA adhered to its *de minimis* policy in responding to the objections on February 25, 1991. *See* Pet. App. 12a.

In its final decision, EPA emphasized the trivial nature of the risks presented by the pesticides to which the *de minimis* policy applied. *See id.* at 32a - 45a. These risks are not actuarial risks based on past experience. There is, in fact, no evidence whatever that anyone has ever contracted cancer from ingesting food treated with any of the pesticides in question. Rather, the risks computed by EPA are upper-bound estimates extrapolated from animal studies to potential human exposures using highly conservative "worst case" assumptions. The agency explained that a risk estimate such as one in one million "does not represent the actual risk" and that the true risk "may, in fact, be lower, even as low as zero." *Id.* at 33a. At most,

such a risk might increase the expected number of cancer cases in a population of one million U.S. residents from 250,000 to 250,001 (an increase of 4/10,000 of one percent). By comparison, similar computed risks are associated with eating one peanut with the maximum permitted level of aflatoxin every 250 days or spending 17 hours per year in miles high Denver, with its greater exposure to radiation. *Id.* at 33a - 34a.

With these facts in mind, EPA reasoned that Congress did not intend an extraordinarily rigid interpretation of the food additive Delaney Clause (21 U.S.C. 348(c)(3)(A)) that would bar approval of pesticides associated with such insignificant risks. The agency reviewed at length "the larger statutory framework involving the regulation of pesticides," and concluded that "interpreting the Delaney Clause as containing a *de minimis* exception helps reduce the conflict in the [Federal Food, Drug, and Cosmetic Act (FFDCA)] and between the FFDCA and [the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)]." *Id.* at 100a. Relying on the statute and well-settled principles of administrative authority, EPA exercised its inherent discretion under the *de minimis* doctrine, and concluded that the law permits continued approval of these pesticides. The contrary result, EPA found, would be unreasonable because it would require that pesticide approvals be revoked on the basis of an essentially nonexistent human risk. *See id.* at 45a - 108a.

2. The court of appeals set aside the order. *Id.* at 1a - 11a. Respondents did not challenge EPA's factual findings, and the court of appeals did not disturb them. Nonetheless, the court held that the Delaney Clause allows EPA "no discretion." *Id.* at 6a - 7a. The court rejected the EPA's contention that a *de minimis* exception to the Delaney Clause is necessary to reconcile the conflicting statutory policies and provisions applicable to pesticides. The court reached this result in large part based on its belief that the Delaney Clause has been

uniformly "interpreted as an absolute bar to all carcinogenic food additives". *Id.* at 9a.

SUMMARY OF ARGUMENT

This Court should grant the petition for a writ of certiorari because the court of appeals erred in failing to defer to EPA's reasonable interpretation of section 409 of the FFDCA, including the Delaney Clause, and that error will have substantial disruptive consequences for the Nation's food supply.

Advances in testing and analytical technologies have made it increasingly clear that virtually the entire food supply contains substances that have been shown in animal feeding studies to be carcinogenic. EPA has identified a large number of valuable pesticides that are animal carcinogens but pose at most a negligible risk to humans. The loss of these pesticides would jeopardize the food supply and threaten consumer health, without providing any compensating public benefit. In addition, many common food substances are animal carcinogens and could be considered food additives subject to the Delaney Clause and therefore banned under the ruling of the court of appeals.

The decision below is manifestly incorrect. EPA acted well within its statutory authority and in a manner entirely consistent with both the legislative history and regulatory precedents. The court of appeals overstepped its authority by relying on blind literalism as an excuse for requiring a rigid and insupportable "zero risk" rule that was never intended by Congress and would wreak havoc with the food supply.

The court of appeals' construction of the statute ignores the doctrine that agencies have inherent authority to address *de minimis* risks in a sensible manner, and that therefore this authority need not be stated expressly in the law. The court also failed even to cite *Chevron U.S.A., Inc.* v. *NRDC*, 467 U.S. 837 (1984), under which it was required to defer to the EPA's reasonable interpretation of the statute. Given the

complexity and internal contradictions of the statutory scheme at issue here, there could be no stronger case in which to heed the wisdom of *Chevron*.

Finally, the Solicitor General urged the Court to deny review in an earlier case involving the color additive Delaney Clause, in favor of review in a food additive case. Such a case is now before the Court, and the reasons given by the Solicitor General in his earlier filing further counsel in favor of review here.

ARGUMENT

I. THE DECISION OF THE COURT OF APPEALS JEOPARDIZES THE NATION'S FOOD SUPPLY.

This case presents an issue of overriding importance to consumers and food producers: whether a substance must be banned merely because it may be carcinogenic in laboratory rats or mice, when any risk to humans is essentially nonexistent. This question is important because virtually every food contains substances meeting this description. The continued lawfulness of these foods is jeopardized by the decision below.

The court of appeals' decision, if allowed to stand, would have a far-reaching detrimental impact on EPA's pesticide regulatory program, the United States' food producers, and consumers. EPA's present policy would compel it to prohibit the use of large numbers of valuable pesticides that have been found to pose trivial risks, and the Agency would be forced to divert limited resources from pesticide regulatory activities of far greater public importance.

Although the court of appeals' decision directly involved tolerances for only four pesticides, EPA has acknowledged that at least thirty, and probably well over sixty, food use pesticides may be required to be banned under the Court's holding. Linda Fisher, EPA Assistant Administrator for Pesticides and Toxic Substances, testified before Congress in July that the loss of these pesticides is likely to have profound adverse consequences

without any measurable contribution to food safety. Statement Before the Subcommittee on Environment, Energy, and Natural Resources of the House Committee on Government Operations (July 23, 1992).

The prohibition of numerous valuable food-use pesticides, as required by the Ninth Circuit decision, would disrupt agricultural production, diminish food quality, increase costs to consumers and reduce the availability and consumption of nutritious fruit, vegetable, and grain products. This would not only cause serious economic harm to food producers and consumers, but would jeopardize consumer health by inhibiting the consumption of the very food products which public health authorities have urged the public to consume in greater quantities. *See, e.g.*, 58 Fed. Reg. 2537-51 (January 6, 1993) (promulgating final FDA rule authorizing health claims for fruits and vegetables relating diets high in these foods to a reduced risk of cancer).

The adverse impact on EPA's pesticide program would be equally dramatic. EPA would be required to undertake lengthy and burdensome administrative proceedings in connection with pesticides required to be banned under the zero risk standard imposed by the Ninth Circuit. This would divert scarce EPA resources from completion of the pesticide reregistration program. Section 4 of FIFRA (7 U.S.C. § 4) requires a complete reexamination, to be completed by 1997, of the human health and environmental effects of all pesticides registered prior to 1988. By triggering scores of tolerance revocation proceedings with respect to pesticides posing *de minimis* risks, the Ninth Circuit decision would hamper the reregistration program and delay the cancellation of truly hazardous pesticides. It would also reduce the resources available for EPA to carry through pesticide regulatory proposals that address numerous other critical safety issues. 57 Fed. Reg. 17389 (April 27, 1992).

Finally, the risk to the public would be increased by forcing EPA to ban beneficial pesticides that pose *de minimis* cancer risks and requiring the substitution of pesticides posing greater health risks which are not associated with cancer. *See* Speech by William K. Reilly before the National Agricultural Chemicals Ass'n Annual Meeting 4 (Sept. 28, 1992).

While the facts before the court of appeals involved pesticides, the same statutory Delaney Clause applies generally to all food additives. Many food additives, such as preservatives, provide important health protection to the American public. In general, food additives of many kinds are essential to the production of a safe, varied, and plentiful food supply. Like certain pesticides, however, some of these food additives have been associated with cancer in animal studies. The court of appeals' decision, if allowed to stand, would call into question the continued approval of these substances.

In fact, trace amounts of animal carcinogens are present in virtually all foods, as FDA has recognized. *See*, *e.g.*, 44 Fed. Reg. 59509, 59513 (October 16, 1979). Advances in testing methodologies have led to the identification of an ever-increasing universe of substances that are animal carcinogens. At the same time, advances in analytical technologies have allowed scientists to identify these trace constituents at ever-lower levels in foods, often measured in parts per billion. The inevitable result of these twin developments has been a showing that the entire food supply contains animal carcinogens at very low levels. These include essential nutrients, such as vitamins and protein; raw agricultural commodities, such as egg yolk; and substances added through food processing, such as salt and water (which contains a number of animal carcinogens). Under the comprehensive FFDCA definition of "food additive," virtually all of these substances could be considered food additives subject to the Delaney Clause. *See* 21 C.F.R. 170.3(e).

Notwithstanding their safety in humans, these substances could be considered unlawful food additives under the decision of the court of appeals. It would cause substantial economic disruption, interfere with the production and availability of a wholesome, varied, and affordable food supply, and adversely affect the public health to interpret the Delaney Clause to require the banning of food additives that present only a *de minimis* risk of cancer.

II. EPA'S *DE MINIMIS* INTERPRETATION OF THE STATUTE IS AUTHORIZED AND REASONABLE.

The court of appeals fundamentally misunderstood the Delaney Clause. That provision was never intended by Congress, and has never been interpreted by the relevant agencies, as the sweeping, absolute barrier that the court below thought it was. There are numerous statutory and administrative exceptions to the Delaney Clause, which belie any notion that the statute is a rigid bar to the use of any animal carcinogen, regardless of the degree of human risk.[1] When both the Delaney Clause and the nature of the agency's authority are fully understood, it will be seen that the *de minimis* policy is amply supported.

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[1] For example, the Delaney Clause does not apply to substances shown to cause cancer in animals through models that are not appropriate or relevant to an evaluation of human safety; secondary carcinogens (substances that cause a physiologic change that causes cancer); carcinogenic contaminants in food within established limits; carcinogenic constituents of food additives and color additives if they pose a *de minimis* risk; carcinogenic animal drugs if their detectable residues pose a *de minimis* risk; carcinogenic substances that are not considered food additives because they are present in amounts that pose a *de minimis* risk; and carcinogens that are ubiquitous in the environment and present in food additives or color additives in amounts that pose a *de minimis* additional risk. *See* pages 18-19 *infra*.

A. Agencies Have Inherent Authority To Exclude *De Minimis* Matters From Regulation.

Just last Term, the Court confirmed that the *de minimis* doctrine "is part of the established background of legal principles against which all enactments are adopted, and which all enactments (absent contrary indication) are deemed to accept." *Wisconsin Dep't of Revenue* v. *William Wrigley, Jr., Co.*, 112 S. Ct. 2447, 2458 (1992). Thus, it has been well established that regulatory agencies have inherent authority to decide not to regulate *de minimis* matters, even where the underlying statute is "without exception or qualification." *Permian Basin Area Rate Cases*, 390 U.S. 747, 787 (1968). In short, federal regulatory statutes are "intended to require the elimination, as far as feasible, of significant risks of harm" rather than "to eliminate completely and with absolute certainty any risk." *Industrial Union Dep't, AFL-CIO* v. *American Petroleum Institute*, 448 U.S. 607, 641 (1980) (pl. op.).

The Court adopted the same principle almost 80 years ago in interpreting the first federal food and drug law, when it held that the prohibition against the addition to food of "any" poisonous or deleterious ingredient that "may render" it "injurious to health" applied only if the substance represented a reasonable possibility of harm to human health: if a food "cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such [food], though having a small addition of poisonous or deleterious ingredients, may not be condemned." *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399, 411 (1914) (interpreting the Food and Drugs Act of 1906).

The *de minimis* principle has retained its vitality under the current FFDCA. When Congress passed the Act in 1938, it preserved the 1906 prohibition, along with the Supreme Court's interpretation of it in *Lexington Mill*. *See* 21 U.S.C. 342(a)(1); *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153,

161 (1958). Other food safety provisions embody the same standard. *See, e.g., United States* v. *1,500 Cases More or Less, Tomato Paste*, 236 F.2d 208, 215 (7th Cir. 1956) (statute's prohibition against "any" filth in food is not violated by quantities "so low that they are * * * insignificant and of no consequence").

The court of appeals departed from this principle by requiring an express statutory source for EPA's *de minimis* authority under the Delaney Clause. As the cases cited above make clear, there is a presumption of *inherent* administrative authority to exclude *de minimis* matters, which can only be overcome by the plainest showing of legislative intent. *See also Alabama Power Co.* v. *Costle*, 636 F.2d 323, 360-61 (D.C. Cir. 1979). No such showing is possible here, because Congress did not expressly deny agencies their inherent *de minimis* powers in the Delaney Clause, and the legislative history shows that Congress similarly did not harbor an intent (unexpressed in the statute) to require agencies to prohibit substances that present *de minimis* risks.

B. The Legislative History Supports The *De Minimis* Policy.

When Congress passed the Food Additives Amendment of 1958, it shifted the burden of proving safety to industry, but it retained the same safety standard adopted in 1906 and 1938, that is, "a reasonable certainty that no harm will result." H.R. Rep. No. 2284, 85th Cong., 2d Sess. 4 (1958); S. Rep. No. 2422, 85th Cong., 2d Sess. 6 (1958). Both the House and Senate emphasized that this standard "does not — and cannot — require proof beyond any possible doubt that no harm will result under any conceivable circumstance." *Id.*

It was in this context that Congress considered whether to add Representative Delaney's proposed anti-cancer clause to the food additive bill. The FDA and its parent, the Department of Health, Education, and Welfare (HEW), initially opposed the

clause on the ground that it was unnecessary in light of the general safety requirement of the bill. *See Food Additives: Hearings Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 85th Cong., 1st & 2d Sess. 38-39 (1957 & 1958). The Administration ultimately dropped its opposition on the assurance that FDA would retain the same scientific discretion under the Delaney Clause that it possessed under the general safety standard. *See* 104 Cong. Rec. 17415 (1958). The Delaney amendment was seen simply as a vehicle "to allay any lingering apprehension * * * of those who desire an explicit statutory mandate on this point." *Id.*

The foregoing quotation is from the same Congressional Record page cited by the court of appeals as its only support for the proposition that HEW interpreted the Delaney Clause as depriving it of all administrative discretion. Pet. App. 9a. We submit that a fair reading of the page shows precisely the opposite. In fact, the Administration there suggested anti-cancer language that would give FDA the desired discretion, language that ultimately was adopted by Congress in virtually identical form.

The Senate Report confirmed the Administration's view that the Delaney Clause did not establish a higher hurdle than the general safety standard itself. The Report expressly stated the Committee's belief that "*the bill reads and means the same with or without the inclusion of the [Delaney] clause.*" S. Rep. No. 2422, *supra*, at 11 (emphasis added). The Report continued, "This is also the view of the Food and Drug Administration." *Id.* Thus, while the clause "focus[ed] our attention on the cancer-producing potentialities of various substances" (*id.* at 10), it did not substantively change the law in any respect.

Because of its last-minute inclusion in the food additive legislation, the Delaney Clause was a major focus of concern in the food industry. FDA Commissioner Larrick personally met

with many industry representatives to emphasize that the Delaney Clause was not rigid or inflexible. He assured them that the legislative history was clear that the clause was to be interpreted and applied identically to the general safety provisions. Based on this assurance, the industry withdrew its opposition to the bill. *See* Brady, *Responsibility, Freedom and the Law*, 17 Food Drug Cosm. L.J. 323, 326 (1962).

The Administration's interpretation of the law after enactment supports the *de minimis* interpretation. A scientific panel convened by the President's scientific advisor reaffirmed that the Delaney Clause must be applied using a "'rule of reason' based on scientific judgment." 106 Cong. Rec. 15380-81 (1960). The report accurately predicted that developments in scientific methodology eventually would allow agencies to estimate "the probability of cancer induction from a particular carcinogen * * * by weighing scientific evidence as it becomes available." *Id.* The report concluded, "an area of administrative discretion based on the rule of reason is unavoidable if the clause is to be workable." *Id.*

C. The Court of Appeals Ignored the *Chevron* Doctrine That Courts Should Defer To Reasonable Agency Interpretations of Inconsistent or Ambiguous Statutory Provisions.

In *Chevron*, 467 U.S. 837, this Court held that courts must defer to a reasonable administrative statutory interpretation rather than substitute their judgment for that of the experts charged by Congress with applying the law. This is the touchstone of judicial review of agency action. The court below ignored this principle, failing even to cite *Chevron*.

The court of appeals apparently thought deference inappropriate because, in its view, EPA departed from unambiguous statutory language. As already discussed, that view ignores the inherent authority both EPA and FDA possess

to exclude *de minimis* risks from regulation. That authority makes the *de minimis* policy a reasonable one, deserving of deference, with respect to any food additive subject to section 409.

The arguments in favor of EPA's decision in this case are all the more compelling because of the complex and conflicting statutory provisions applicable to pesticides. In critical respects, the statutory scheme governing pesticides is ambiguous and uncertain. EPA's policy at issue here represents precisely the sort of pragmatic administrative reconciliation of unclear statutory directives to which the courts are required to pay deference. The court below failed to appreciate how EPA's decision faithfully implements a reasonable interpretation both of the statutory language and of the congressional design. Had the court done so, it would have been required to uphold that decision under *Chevron*.

The "precise question" (467 U.S. at 842-43) in this case is whether residues of an approved pesticide that concentrate in processed food must be forbidden entirely if the pesticide includes cancer in experimental animals even though the residues may be approved in the raw commodity and even though they would be lawful in the processed food if they did not concentrate. More generally, the issue is how Congress wished the risk of carcinogenicity to be addressed under the three statutory provisions that govern the use of pesticides in food production -- FIFRA, section 408 of the FFDCA (the Miller Pesticide Amendment of 1954), and section 409 of the FFDCA (the Food Additives Amendment), which alone includes the Delaney Clause. A balanced, thorough analysis of these laws, including the history of the Food Additives Amendment, demonstrates that Congress did not specifically address this question.

In denying the petition for revocation of four pesticides on the grounds that they pose only a *de minimis* risk, EPA

recounted at some length the inconsistent standards and overlapping coverage of sections 408 and 409 of the FFDCA, and of the FIFRA. Pet. App. 13a - 25a. *See* National Research Council, *Regulating Pesticides in Food: The Delaney Paradox* (1987). Briefly stated, EPA must consider the degree of risk posed by a pesticide and the benefits it provides in establishing a tolerance under section 408 for residues of the pesticide on a raw commodity. A number of carcinogenic pesticides have been approved under section 408 on the ground that they present only a negligible risk of cancer. Under the flow-through provision of section 402(a)(2)(C), residues of approved pesticides — including carcinogens — that remain in the commodity after processing are permitted if they do not exceed the section 408 tolerance. Residues that concentrate in the processed food above the raw product tolerance level are deemed by EPA to render the food adulterated unless they are sanctioned by a supplemental section 409 food additive regulation. But if the pesticide presents even a trivial risk of cancer, the Delaney Clause in section 409 — which has no counterpart in section 408 — may be read as precluding issuance of a food additive regulation. As a result, "the same pesticide residues which may be legal on a raw food could render a processed food adulterated" if the pesticide concentrates during processing. *Id.* at 20a.

In order to avoid this "Delaney paradox" in the regulation of pesticides that involve only a negligible risk of cancer, EPA concluded that it could reconcile the apparently conflicting messages of the statute by interpreting the Delaney clause in section 409 as not precluding approval of residues that posed only a *de minimis* risk of cancer. The agency reasoned:

> [t]here is sufficient flexibility in the statutory framework to apply a standard to the evaluation of pesticides under section 409 which both

> ameliorates the most extreme effects of the Delaney paradox and protects the public health.

Id. at 15a. The court of appeals refused to accept EPA's adoption of a *de minimis* gloss on the Delaney Clause as a means of reconciling the inconsistent safety standards of sections 408 and 409 as they apply to pesticide residues in raw and processed foods. In reaching this conclusion, the court claimed:

> The statute unambiguously provides that pesticides which concentrate in processed food are to be treated as food additives, and these are governed by the Delaney food additive provision contained in section 409. If pesticides which concentrate in processed foods induce cancer in humans or animals, they render the food adulterated and must be prohibited.

Id. at 8a.

Contrary to the court of appeals' assertion, there could be no stronger case for application of *Chevron*'s wise guidance to reviewing courts. Yet the court of appeals did not simply fail to follow this Court's guidance; it wholly ignored *Chevron*, dismissed EPA's painstaking effort to reconcile the divergent directives of the laws it is responsible for administering, and substituted its own, self-described "plain meaning" interpretation of a set of statutory provisions whose precise meaning in this context is ambiguous at best.

The court's conclusory assertion that the Act is clear and unambiguous in its application to pesticide residues in processed foods is squarely contradicted by the language of the Act itself. The definition of a "food additive" in section 201(s) of the FFDCA includes exceptions not only for a pesticide residue "in or on" a raw agricultural commodity, and for a pesticide "intended for use" on such commodities, but also for a pesticide "to the extent that it * * * is used" on a raw commodity. On

its face this latter exception precludes regulation of a pesticide as a food additive to the extent that it "is used" on an agricultural commodity, whether or not the commodity is subsequently processed or otherwise altered.[2]

The exception in section 201(s)(2) for a pesticide that "is used" on an agricultural commodity was added late in the 1958 legislative process by the House Committee as one of several "clarifying changes" in the bill, but without further explanation. 104 Cong. Rec. 17414 (Aug. 13, 1958); *compare* H.R. 13254, 85th Cong., 2d Sess. (July 1, 1958), p. 2, lines 17-18; *with* H.R. 13254, 85th Cong., 2d Sess., as reported (July 28, 1958), p. 19, line 2. Neither the Committee Report nor the floor debate referred to the inconsistency between the section 201(s)(2) exclusion of a pesticide from food additive regulation once it is used on a crop, and the flow-through provision in section 402(a)(2)(C) providing that a pesticide residue in a processed food will not be deemed unsafe under section 409 (and its Delaney Clause) if the concentration of the pesticide is not greater than the section 408 tolerance for the pesticide on the raw commodity. If section 201(s)(2) means what it says, there appears to be no point to the flow-through language of section 402(a)(2)(C). In administering the pesticide provisions of the Act, both FDA prior to 1970, and EPA thereafter, have chosen to overlook the section 201(s)(2) food additive exception for a pesticide that is used on a crop, and instead have promulgated food additive regulations under section 409 for approved pesticides that may concentrate in processed foods.

This approach of issuing a food additive regulation for a

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[2] In *United States* v. *Ewig Bros. Co.*, 502 F.2d 715 (7th Cir. 1974), the court held that DDT residues in processed fish resulting from environmental contamination, rather than from the lawful use of the pesticide in the production of the raw fish, were subject to regulation as food additives. The court was thus not faced with application of the exception in section 201(s)(2) for a pesticide "to the extent that it is * * * used in the production * * * of any raw agricultural commodity."

pesticide that concentrates in processed food not only sidestepped the statutory interpretation issue posed by section 201(s)(2). It also made it unnecessary for the agency to interpret and apply the requirement in the flow-through provision of section 402(a)(2)(C) that the residue in the processed food "*when ready to eat*" must not exceed the raw product tolerance. Rather than attempting to evaluate pesticide residues in concentrated processed foods at the enforcement stage by applying the imprecise "when ready to eat" standard, EPA has chosen to avoid uncertainty in compliance and enforcement by issuing easily applied section 409 regulations.

EPA's decision to issue food additive regulations for pesticides that may concentrate in processed foods appeared to make good regulatory sense. Strict application of the section 201(s)(2) exception would leave such residues subject to regulation only under the general safety standard of section 402(a), rather than under the licensing provisions of section 409. Furthermore, the issuance of food additive regulations based on an assumed concentration factor had the added benefit of avoiding the difficulty in applying the "when ready to eat" enforcement standard in section 402(a)(2)(C). It does not appear that EPA ever publicly addressed the significance of "or is used" in section 201(s)(2) or "when ready to eat" in section 402(a)(2)(C), or that those affected by pesticide regulation publicly objected to EPA's practice of issuing section 409 regulations for pesticides that concentrated in processed foods. This *sub silentio* approach to these issues is understandable, for EPA would have no reason to raise questions concerning its own implementation of the Act, and the affected industries (pesticide makers, farmers, and processors) were apparently content with the practical effectiveness of the EPA approach.

Problems with the EPA practice of requiring section 409 regulations for pesticides that concentrate in processed foods began to arise, however, when a number of approved pesticides

were found to be animal carcinogens. The benefit/risk standard of section 408 authorized EPA to ignore negligible risks, including a risk of cancer, but the Delaney Clause in section 409 clearly threatened the legal status of pesticides in some processed foods. This puzzling interplay among sections 408, 409, and 402(a)(2)(C) gave rise to the paradoxical result that a carcinogenic pesticide would be allowed in processed foods that do not concentrate, but forbidden in those that do. After extensive review of the issue by the EPA and by the special NAS Committee in *The Delaney Paradox*, the agency concluded that interpretation of the Delaney Clause to incorporate a *de minimis* risk exception would advance the diverse goals of pesticide regulation under section 408, food additives regulation under section 409, and Congress' attempt to reconcile them in section 402(a)(2)(C). Pet. App. 12a.

It can thus be seen that the EPA *de minimis* policy serves as a means of reconciling inconsistent, overlapping and ambiguous statutory language concerning the status of pesticide residues in processed foods. Under these circumstances, the court of appeals decision is squarely at odds with *Chevron*'s demand for deference and with this Court's application of that requirement to interpretation of the adulteration provisions of the FFDCA. *See Young* v. *Community Nutrition Institute*, 476 U.S. 974, 980-81 (1986) (reversing a court of appeals decision that failed to defer to the FDA's interpretation of ambiguous language in section 406 of the FFDCA).

III. THE *DE MINIMIS* POLICY IS CONSISTENT WITH ADMINISTRATIVE PRACTICE.

The court of appeals based its decision in part on its belief that the Delaney Clause has been interpreted as "an absolute bar to all carcinogenic food additives." Pet. App. at 9a. This understanding of administrative practice is erroneous. In fact, the *de minimis* policy is consistent with FDA's and EPA's historical and present implementation of the Delaney Clause.

Through the *de minimis* interpretation and other policies under the Delaney Clause, the agencies have sought to protect the public from real risks while avoiding the needless prohibition of substances that are associated with at most a trivial risk of cancer.

Prior to 1958, FDA interpreted the general safety clauses of the FD&C Act to bar the use of animal carcinogens because the state of toxicology did not then permit the assessment of human risks. *See*, *e.g.*, 15 Fed. Reg. 321 (January 19, 1950); 19 Fed. Reg. 1239 (March 5, 1954). FDA continued the same policy after enactment of the Delaney Clause. In the only two cases in which it applied that provision before 1973, it banned two carcinogenic additives without attempting to determine what magnitude of risk they presented, since the analytical tools to do so were not yet sufficiently developed. *See* 32 Fed. Reg. 5675 (April 7, 1967); 34 Fed. Reg. 19073 (December 2, 1968).

Beginning in 1973, FDA has consistently used the newly available techniques of quantitative risk assessment to approve or permit the continued use of substances that present only a *de minimis* risk of cancer. *See* P. Hutt & R. Merrill, *Food and Drug Law*, chapter 8 (2d ed. 1991). These agency decisions follow logically from the 1958 contemporaneous administrative interpretation of the Delaney Clause as embodying the same scientific discretion that is inherent in the other safety provisions of the Act. *See* page 10, *supra*. As science has continued to develop, FDA has used the tools at its command to protect the public health from genuine risks, while at the same time recognizing that the public health is not served by needlessly banning substances that do not present any cognizable risk of human cancer.

For example, under FDA's "constituents policy," a carcinogenic impurity or other constituent of a food additive or color additive is not subject to the Delaney Clause, and thus the additive as a whole can be approved under the general safety

provisions, if use of the additive presents only an insignificant carcinogenic risk. The Sixth Circuit upheld this policy in *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984) (per curiam). Similarly, carcinogenic substances that migrate from food contact materials into food may be excluded from the definition of "food additive" if their use presents only a *de minimis* risk of cancer. *See Monsanto Co.* v. *Kennedy*, 613 F.2d 947 (D.C. Cir. 1979). By the same logic, substances that present a *de minimis* cancer risk can be regarded as generally recognized as safe (GRAS) and therefore similarly excluded from the food additive definition. *See Public Citizen* v. *Young*, 831 F.2d 1108, 1119-20 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 1006 (1988). While policies such as these are not in dispute in this case, they demonstrate the reasonableness of the *de minimis* policy and its consistency with other FDA public health initiatives.

EPA also has applied the "constituents policy" in granting food additive approval for the pesticide dicamba in sugarcane molasses. 48 Fed. Reg. 50528 (November 2, 1983). EPA concluded that the nitrosamine contaminant in dicamba, although an animal carcinogen, posed only a *de minimis* human cancer risk. Thus, contrary to the Ninth Circuit's holding, both FDA and EPA historically have applied *de minimis* principles in interpreting section 409 and the Delaney Clause.

IV. THE SOLICITOR GENERAL'S OPPOSITION TO REVIEW IN THIS CASE IS INCONSISTENT WITH HIS POSITION IN AN EARLIER COLOR ADDITIVE CASE.

The government's opposition to the petition in this case is inconsistent with the Solicitor General's position before this Court in a case involving the color additive Delaney Clause, *Cosmetic, Toiletry and Fragrance Ass'n* v. *Public Citizen*, No. 87-1194. There, the government opposed a certiorari petition filed by the industry intervenor principally on the grounds that the Court should wait for a food additive case (which would be

more important as a practical matter and would more directly implicate the critical 1958 legislative history) and that the views of the relevant agencies, including EPA, had not yet been finalized. *See* Gov't Br. in Opp., No. 87-1194, at 7-9. The present case arises directly under the 1958 food additive Delaney Clause, and the government's administrative interpretation of that provision has now been established, as shown by EPA's lengthy Federal Register notice announcing, explaining, and applying the *de minimis* policy. The government's opposition to the present petition thus represents a 180-degree shift from its earlier position before this Court. While the government notes that EPA is currently considering a change in its pesticide tolerance policy (Br. in Opp. 8-9), that fact alone provides no basis for denying the petition here. The possibility that EPA might at some unknown time in the future change its tolerance policy as a response to the decision below does not refute the substantial adverse impact of that decision, which represents a final judicial determination that the *de minimis* policy is invalid.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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